

EXHIBIT B

SHERIFF'S RETURN

State of Alabama Unified Judicial System Form C-34 Rev 6/88	SUMMONS - CIVIL -	Case Number <div style="font-size: 1.2em; font-family: cursive;">CW06-210</div>
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IN THE _____ Circuit _____ COURT OF _____ Lee _____ COUNTY

Plaintiff Andrea Holifield v. Defendant Eli Lilly & Company, Et al.

801 P2A ✓
Skyway Drive

NOTICE TO D2 [REDACTED]

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY _____ JOSEPH L. TUCKER _____ WHOSE ADDRESS IS _____ Black Diamond Building 2229 First Avenue North, Birmingham, Alabama 35203 _____.

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN 30 DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

RECEIVED

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure MAR 24 2006

☒ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☐ Service by certified mail of this summons is initiated upon the written request of _____ pursuant to the Alabama Rules of Civil Procedure.

Date 3/23/06 Corinne T Hurst By: sz
Clerk/Register

☐ Certified Mail is hereby requested.

Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

☒ I certify that I personally delivered a copy of the Summons and Complaint to _____ (Date)
Dr. Lusha O'Brien in Lee County,
Alabama on 5-4-06 (Date)

Date

Address of Server

Server's Signature

Type of Process Server

IN THE CIRCUIT COURT OF LEE COUNTY, ALABAMA

FILED

MAR 23 2006

IN OFFICE
CORINNE T. HURST
CIRCUIT CLERK

ANDREA HOLIFIELD, an individual,)

Plaintiff,)

vs.)

CIVIL ACTION NO.: CV 06-210

Eli Lilly and Company, a corporation; PETER LUSCHE, M.D., an individual; Fictitious parties Defendant, A, B, C, D, & E, being the correct name of any of the aforementioned Defendants who are known only to Plaintiff by the name(s) listed above; F, G, H, I, and J, being those persons, entities and/or individuals, whether singular or plural, who or which manufactured a certain drug known as Zyprexa; K, L, M, N, and O, being those persons, entities or individuals, whether singular or plural, who or which sold, distributed, marketed or had any role in the distributive chain regarding the drug made the basis of this suit, including, but not limited to, marketing, selling, advertising, distributing, and/or promoting the drug as the agent, servant or employee of Eli Lilly and Company, or in the capacity of sales representative disseminating information to physicians or their representative staff, or pharmacist or their representative staff concerning, among other things, the safety, efficacy and/or use of the drug made the basis of this suit; P, Q, R, S, and T, being those persons, entities or individuals, whether singular or plural, who or which sold, distributed, marketed or had any role in the distributive chain regarding the drug made the basis of this suit, including, but not limited to, marketing, selling, advertising, distributing, and/or promoting the drug as the agent, servant or employee of any named or fictitiously described Defendant, in any capacity including that of sales representative disseminating information to physicians or their representative staff, or pharmacist or their representative staff concerning, among other things, the safety, efficacy and/or use of the drug made the basis of this suit; U, V, and W, being those persons, entities or individuals, whether singular or plural, other than those named or fictitiously described Defendants described above, which are the successors in interest of any of those entities described above. (Plaintiff avers that the identities of the fictitious parties Defendant herein are otherwise unknown to the Plaintiff at this time or, if their names are known to Plaintiff, their identities as proper parties Defendant are not known to Plaintiff at this time, and their true names will be substituted by amendment when ascertained.)

Defendants.)

COMPLAINT

1. This is a medical negligence and pharmaceutical product liability lawsuit Plaintiff ANDREA HOLIFIELD suffers from Diabetes Type 2 as a result of ingestion of a prescription medication sold as Zyprexa. Plaintiff's awareness of the substantial risks of this condition is a source of incredible anguish to Plaintiff.

SPANNED

PARTIES

2. Plaintiff ANDREA HOLIFIELD is over nineteen years of age and is a resident of LEE County, Alabama. Plaintiff ingested the pharmaceutical drug olazapine, also known by the brand name Zyprexa, manufactured, marketed, distributed, packaged, promoted and/or sold by Defendant Eli Lilly and Company and prescribed to Plaintiff by Defendant PETER LUSCHE, M.D.

3. Defendants are as follows:

3.1 Defendant PETER LUSCHE, M.D., is an individual and physician, and a resident and citizen of Alabama. The doctor was the physician for Plaintiff and prescribed the drug in question to Plaintiff. PETER LUSCHE, M.D. may be served at the doctor's principal place of business at the following address: 3120 Frederick Road, Opelika, AL 36801. At all relevant times, the doctor was a licensed physician in the State of Alabama, doing business in Alabama.

3.2 Defendant Eli Lilly and Company is organized and existing under the laws of the State of Indiana. Eli Lilly and Company does business in the State of Alabama and, at all relevant times, was in the business of promoting, marketing, manufacturing and distributing the pharmaceutical Zyprexa in the State of Alabama. Plaintiff intends to sue that group, corporation(s), partnership(s) or association(s) doing business as Eli Lilly & Company, who manufactured, promoted, marketed, sold and distributed the drug Zyprexa to pharmacies and physicians worldwide and in the United States, and specifically in Texas. Plaintiff reserves the right, if needed, to add or amend any formal names to properly reflect the correct party. Eli Lilly and Company and may be served through its registered agent, indicated below, at the following address:

National Registered Agents, Inc.
150 S. Perry Street
Montgomery, AL 36104

3.3. Fictitious parties Defendants, A, B, C, D, & E, being the correct name of any of the aforementioned Defendants who are known only to Plaintiff by the name(s) listed above; F, G, H, I, and J, being those persons, entities and/or individuals, whether singular or plural, who

or which manufactured Zyprexa; K, L, M, N, and O, being those persons, entities or individuals, whether singular or plural, who or which sold, distributed, marketed or had any role in the distributive chain regarding the drug made the basis of this suit, including, but not limited to, marketing, selling, advertising, distributing, and/or promoting the drug as the agent, servant or employee of Eli Lilly and Company, or in the capacity of sales representative disseminating information to physicians or their representative staff, or pharmacist or their representative staff concerning, among other things, the safety, efficacy and/or use of the drug made the basis of this suit; P, Q, R, S, and T, being those persons, entities or individuals, whether singular or plural, who or which sold, distributed, marketed or had any role in the distributive chain regarding the drug made the basis of this suit, including, but not limited to, marketing, selling, advertising, distributing, and/or promoting the drug as the agent, servant or employee of any named or fictitiously described Defendant, in any capacity including that of sales representative disseminating information to physicians or their representative staff, or pharmacist or their representative staff concerning, among other things, the safety, efficacy and/or use of the drug made the basis of this suit; U, V, and W, being those persons, entities or individuals, whether singular or plural, other than those named or fictitiously described Defendants described above, which are the successors in interest of any of those entities described above. (Plaintiff avers that the identities of the fictitious parties Defendant herein are otherwise unknown to the Plaintiff at this time or, if their names are known to Plaintiff, their identities as proper parties Defendant are not known to Plaintiff at this time, and their true names will be substituted by amendment when ascertained.)

JURISDICTION AND VENUE

4. The Court has jurisdiction over each Defendant because each Defendant is doing business in Alabama, has committed a tort in whole or in part in Alabama, is a resident and citizen of the State of Alabama, and/or has continuing minimum contacts with the State of Alabama. Each

Defendant is amenable to service of process by an Alabama Court. This Court also has jurisdiction over the controversy because the damages are above the minimum jurisdictional amounts.

5. Venue is proper in LEE County because all or part of the causes of action accrued in LEE County, and because some or all of the Defendants either reside in or conduct business in LEE County by distributing, selling, and/or marketing their products in LEE County.

6. There is no basis for federal court jurisdiction over this matter:

- a. Plaintiff has not pled nor does Plaintiff intend to plead any claim cognizable under federal law or any federal code, regulation, rule, statute, or otherwise;
- b. There is no diversity of citizenship between Plaintiff and all Defendants;
- c. No Defendant may remove pursuant to the *All Writs Act*, because neither this lawsuit nor any of the Plaintiff's claims threaten to frustrate or damage the integrity of a settlement in any federal suit; and/or
- d. In the event any Defendant files a notice of removal premised on "fraudulent joinder," as has repeatedly been done in other lawsuits filed in state court, Plaintiff hereby asserts the removal will be without any good faith legal basis or legal justification and will be entirely for the purpose of avoiding the jurisdiction of this Honorable Court. Plaintiff hereby gives notice of intent to seek sanctions for any improper removal.

FACTUAL BACKGROUND

7. At all relevant times, Defendant Eli Lilly and Company (herein after sometimes referred to the Drug Company Defendant), itself, or by use of others, did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, advertise, and/or otherwise distribute, in interstate commerce the atypical anti-psychotic prescription medication Zyprexa.

8. Plaintiff is complaining of injuries sustained as the result of the use of Zyprexa prescribed by Plaintiff's treating physician, Defendant PETER LUSCHE, M.D., for treatment of

depression from approximately September 21, 2003 to July 5, 2005.

9. As a result, Plaintiff suffered physical injury and damages arising from the prescription and ingestion of Zyprexa, including but not limited to one or more of the following: diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and/or diabetic coma, as well as other severe and permanent health consequences proximately caused in whole or in part by the conduct of defendants.

10. Zyprexa is the brand name for olanzapine, a drug belonging to a class that is sometimes referred to as the new generation or atypical antipsychotics. Clozapine (brand name Clozaril), manufactured by Novartis, quetiapine (brand name Seroquel) manufactured by AstraZeneca; risperidone (brand name Risperdal) manufactured by Janssen, and ziprasidone (brand name Geodon), manufactured by Pfizer, are also members of this class.

11. There are other antipsychotic medications, including Haldol, Thorazine, Prolixin, Navane, Stelazine, Trilafon, and Mellaril, that are alternatives to the atypical antipsychotics.

12. Zyprexa was developed by Lilly and approved by the FDA in 1996 for the treatment of schizophrenia. Since its initial approval for the treatment of schizophrenia, Zyprexa has also been approved for the treatment of short-term bi-polar mania, in combination with lithium or valproate for treatment of bi-polar mania, in combination with Prozac for treatment of bi-polar depression, and for bi-polar disorder maintenance. In 2004, an injectable form of Zyprexa was approved for use as a fast-acting treatment for acute agitation associated with schizophrenia and bi-polar disorder.

13. Since the introduction of the new generation atypical antipsychotic medications, beginning with clozapine in 1990, case reports in the literature suggested that drugs of that class might be associated with new onset of diabetes mellitus as well as with diabetic ketoacidosis.

14. Discussions of the recognized relationship between atypical antipsychotic drugs, weight gain, glycemic control and diabetes have long appeared in medical literature¹. For example, in Effect of Clozapine-Quetiapine Combination Therapy on Weight and Glycaemic Control published in Clinical Drug Investigation in August 1999, the authors discussed combination drug therapy to combat the weight gain and lack of glycemic control. The propensity of the atypical antipsychotics to cause weight gain, hyperlipidemia, diabetes has also long been discussed at conferences, such as the 52nd Institute on Psychiatric Services held by the American Psychiatric Association held in Philadelphia in October 2000. Case reports in medical literature continued to document an association between atypical antipsychotic medications and diabetes mellitus. See Muench, et al, Diabetes Mellitus Assoc. with Atypical Antipsychotic Medications: New Case Report and Review of the Literature, J. Am. Board Fam. Pract. 14(4):278 – 282, 2001.

15. Between April 1996 and May 2001, the FDA received several reports of hyperglycemia, worsening of existing diabetes, pancreatitis, and other severe injuries among children who were prescribed Zyprexa.

16. In December 2000, the *British Medical Journal* found no clear evidence that Zyprexa or other atypical antipsychotics were more effective or better tolerated than conventional antipsychotics including Haldol and Thorazine.

17. In November 2001, the *Journal of the American Medical Association* reported a link between the use of Zyprexa by adolescents and development of hyperglycemia.

18. In July 2002, a study conducted at Duke University further established a relationship between Zyprexa and diabetes. This study documented nearly 300 cases of diabetes among people using Zyprexa.

¹ For a review of the medical literature from 1996, please see Muench, et al., Diabetes Mellitus Assoc. with Atypical Antipsychotic Medications: New Case Report and Review of the Literature, J. Am. Board Fam. Pract. 14(4): 278-282, 2001.

19. In April 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed Zyprexa in its newsletter *Current Problems in Pharmacovigilance*. This newsletter reported forty (40) reports of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Defendant to warn British consumers about the risk of diabetes and diabetic ketoacidosis, and to further required Defendant to instruct British patients who were using Zyprexa to monitor their blood sugar levels.

20. In April 2002, the Japanese Health & Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and diabetic coma for Japanese patients prescribed Zyprexa.

21. In November 2003, the *Journal of the American Medical Association* compared Zyprexa with Haldol and found “no statistically or significant advantages” of Zyprexa for treatment of schizophrenia. The authors did note a significant difference among the costs of Haldol and Zyprexa per tablet: \$0.02 versus \$4.84 respectively.

22. In January 2004, a panel consisting of the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for Study of Obesity issued statement advising doctors to screen and monitor patients taking atypical or second generation anti-psychotics for rapid weight gain or other problems that can lead to diabetes, obesity, high cholesterol, and heart disease. The panel recommended baseline screening for personal and family history of obesity, diabetes, high cholesterol, hypertension, and heart disease.

23. In the 2005 Physician’s Desk Reference, Eli Lilly and Company’s entry for Zyprexa contained information regarding the risk of hyperglycemia and diabetes.

24. There is no valid scientific evidence to support the contention that Zyprexa is safe and effective for treatment of any off-label use, including any use in children.

COUNT I
PHYSICIAN CONDUCT - MEDICAL NEGLIGENCE

25. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and further alleges as follows:

26. Defendant PETER LUSCHE, M.D., prescribed the drug at issue and knew or should have known that the drug was unreasonably dangerous and/or would cause injury to Plaintiff.

27. This Doctor Defendant also failed to adequately and properly warn the Plaintiff about the possible side effects and dangers associated with taking the drug at issue, including, but not limited to weight gain, glucose intolerance, pancreatitis, hyperglycemia, diabetes, and related injuries. Further, after the product labeling was changed, this Doctor Defendant failed to advise and/or recommend that Plaintiff monitor weight or blood sugar and/or obtain any other medical or test which could have prevented and/or minimized the injuries complained of herein.

28. Plaintiff reasonably relied upon the skill and judgment of this Doctor Defendant to provide reasonably prudent medical care, including, but not limited to, the determination of whether the drug at issue was medically safe and appropriate given Plaintiff's medical history and physical condition. Further, the Plaintiff reasonably relied upon this Doctor Defendant, to advise as to alternative safer medications, other medications that had been approved for Plaintiff's condition, that the medication was not approved for Plaintiff's condition, the dangers of the drug that this Defendant prescribed to Plaintiff, and/or the need to undergo preventive examinations to identify any potential injuries caused by the drug, in a reasonable and timely fashion.

29. Contrary to the expectations of the Plaintiff, this Defendant failed to exercise the ordinary care and diligence exercised by other physicians in the same or similar circumstances. Therefore, he failed to act as a reasonably prudent physician and failed to meet the appropriate medical standards for the community, which require him to provide safe and effective treatment to patients, including the Plaintiff. Indeed, whether by his own negligence or through misplaced reliance on the

representations of Eli Lilly & Company and/or any other named or fictitious Defendant, this Doctor Defendant's acts and/or omissions proximately and directly resulted in injury and/or damage to the Plaintiff. Thus, this Doctor Defendant was negligent in his care and treatment of the Plaintiff.

30. This Doctor Defendant failed to exercise the ordinary care and diligence exercised by other physicians in the same or similar circumstances. Although this Doctor Defendant became aware, or as a reasonable and prudent physician should have become aware, of the association between Zyprexa and hypoglycemia, diabetes, and/or diabetes related problems, this Doctor Defendant never alerted Plaintiff to the possible dangers or advised Plaintiff to monitor blood sugars or undergo any examination, and/or other diagnostic testing to determine if Plaintiff had sustained injuries. Therefore, this Doctor Defendant wholly failed to act as a reasonably prudent physician and wholly failed to meet the appropriate medical standards in the community, which require this Doctor Defendant to provide safe and effective treatment to patients, including Plaintiff. Consequently, this Doctor Defendant was negligent in the care and treatment of the Plaintiff.

31. As a direct and proximate result of the breach of care by this Doctor Defendant, Plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein.

32. To the extent this Doctor Defendant and/or any other Defendant, named or fictitious, may assert the statute of limitations and/or statute of repose as affirmative defenses, Plaintiff invokes the discovery rule. This suit was instituted within two (2) years of the Plaintiff first being conclusively diagnosed with an injury as a result of Zyprexa ingestion and knew or should have known about the relationship between that ingestion and the injuries complained of herein. Additionally or in the alternative, the statute of limitations and/or statute of repose is equitably tolled as to this Doctor Defendant as a result of his fraudulent concealment of the dangers of Zyprexa and/or failure to advise the Plaintiff of the possible dangers associated with the drug, and/or his failure to alert the Plaintiff of the need to undergo evaluation and/or diagnostic testing to determine if Plaintiff had sustained injuries. This Doctor Defendant should be estopped from asserting the affirmative defenses of limitations or

repose because, as a physician occupying a confidential relationship with the Plaintiff as a treating physician, this Doctor Defendant had a duty to warn Plaintiff of the dangers of Zyprexa use and Plaintiff relied on this Defendant's advice, or lack thereof, to Plaintiff's detriment.

33. Additionally or in the alternative, due to this Doctor Defendant's misrepresentation and/or concealment and the Plaintiff's lack or means of knowledge of the truth, the Plaintiff invokes the doctrine of equitable estoppel.

34. As a direct and proximate result of the actions, inactions, and/or omissions of this Doctor Defendant, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, lack of glycemic control, diabetes, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendant, PETER LUSCHE, M.D., for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT II
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE

35. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and additionally or in the alternative, if same be

necessary, further alleges as follows:

36. At all times material hereto, the Defendants, individually and collectively, have engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Zyprexa, that was defective and unreasonably dangerous to the Plaintiff.

37. At all times material hereto, the Zyprexa sold, distributed, supplied, manufactured, marketed and/or promoted by the Defendants was expected to reach, and did reach the Plaintiff without substantial change in the condition in which it was sold.

38. At all times material hereto, the drug sold, distributed, supplied, manufactured, marketed and/or promoted by the Defendants was defective in design and unreasonably dangerous at the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting the Plaintiff to risks and which exceeded any benefits of the drug;
- b. When placed in the stream of commerce, the drug was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than risks associated with alternative treatment;
- c. The drug was insufficiently tested;
- d. The drug was not accompanied by adequate instructions and/or warnings to fully inform of the full nature or extent of the risks and side effects associated with its use.

39. The dangers and risks of harm posed by the drug were reasonably foreseeable and/or known to the Defendants. Moreover, the dangers and foreseeable risks of harm associated with the drug was sufficiently great in relation to the purported benefits of the drug, which were nonexistent or negligible at best, so that the drug could not have been properly prescribed to any class of patients, including the Plaintiff.

40. But for the aforementioned defective and unreasonably dangerous conditions, the drug would not have been prescribed to the Plaintiff and the Plaintiff would not have sustained the injuries alleged herein.

41. As a direct and proximate result of the defective condition of the drug, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, lack of glycemic control, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT III
FAILURE TO WARN

42. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and additionally or in the alternative, if same be necessary, further alleges as follows:

43. The drug at issue was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert the Plaintiff to the dangerous risks and reactions associated with the drug, including, but not limited to, hyperglycemia, lack of glycemic control, diabetes, pancreatitis, and/or other serious and life threatening side effects.

44. Plaintiff used the drug for its intended purpose and/or as promoted and/or prescribed.

45. Plaintiff could not have discovered any defect in the drug through the exercise of reasonable care.

46. Defendants, as manufacturers, distributors, and/or sellers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

47. Plaintiff did not have substantially the same knowledge as Defendants and no adequate warnings were communicated to Plaintiff.

48. The warnings that were given by the Defendants to Plaintiff were inadequate, insufficient, inaccurate, and/or ambiguous.

49. The Defendants had a continuing duty to warn Plaintiff of the risks and dangers associated with the drug, which were foreseeable and/or known to the Defendants.

50. As a direct and proximate result of the Defendants' failure to warn, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, lack of glycemic control, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT IV
BREACH OF WARRANTY OF MERCHANTABILITY

51. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and additionally or in the alternative, if same be necessary, further alleges as follows:

52. When Defendants placed the drug into the stream of commerce, they knew of the use for which the drug was intended and expressly and/or impliedly warranted to the Plaintiff that use of the drug was safe and acceptable.

53. Plaintiff reasonably relied upon the expertise, skill, judgment, and knowledge of Defendants and upon the express and/or implied warranty that the drug was of merchantable quality and fit for use.

54. The drug was not of merchantable quality and were not safe or fit for intended use because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which it was used, in that it caused injury to the Plaintiff. The Defendants breached said warranties because the drug was unduly dangerous and did cause injury to the Plaintiff.

55. As a direct and proximate result of the Defendants breach of these warranties, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, lack of glycemic control, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and

- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT V
NEGLIGENCE

56. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and additionally or in the alternative, if same be necessary, further alleges as follows:

57. Defendants, directly and/or indirectly, individually and collectively, negligently made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold, in the State of Alabama, the drug at issue.

58. At all times material hereto, Defendants had a duty to the Plaintiff to exercise reasonable care in the creation, manufacture, assembly, design, testing, labeling, supplying, packaging, distribution, promotion, marketing, advertising, warning, and/or sale of the drug at issue.

59. Defendants breached that duty and were negligent in their actions, misrepresentations, and omissions toward the Plaintiff in the following ways:

- a. Failed to include adequate warnings with the drug that would alert to the potential risks and serious side effects of the drug;
- b. Failed to adequately and properly test the drug before placing it on the market;
- c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, hyperglycemia, lack of glycemic control, injury to the pancreas, diabetes, and/ or other serious and life threatening side effects;
- d. Failed to provide adequate post-marketing warnings or instructions after the Defendants knew or should have known of the significant risks serious and life threatening side

effects, including diabetes and death;

- e. Encouraged misuse and overuse, while underplaying the side effects, in order to profit from sales.

60. Defendants knew or should have known that the drug caused unreasonably dangerous risks and serious side effects, of which the Plaintiff could not be aware. Defendants nevertheless aggressively advertised, marketed, sold and/or otherwise distributed the drug knowing that there were safer, alternative methods and/or products.

61. As a direct and proximate result of the negligence and/or omissions of Defendants, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT VI
WANTONNESS

62. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein and additionally or in the alternative, if same be necessary, further alleges as follows:

63. Defendants, directly and/or indirectly, individually and collectively, negligently made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold, in the State of Alabama, the drug at issue.

64. At all times material hereto, Defendants had a duty to the Plaintiff to exercise reasonable care in the creation, manufacture, assembly, design, testing, labeling, supplying, packaging, distribution, promotion, marketing, advertising, warning, and/or sale of the drug at issue.

65. Defendants breached that duty and were negligent in their actions, misrepresentations, and omissions toward the Plaintiff in the following ways:

- a. Failed to include adequate warnings with the drug that would alert the Plaintiff to the potential risks and serious side effects of the drug;
- b. Failed to adequately and properly test the drug before placing the drug on the market;
- c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, significant risk of diabetes, hyperglycemia, pancreatitis, damage and diseases, and/or other serious and life threatening side effects;
- d. Failed to adequately warn that use of the drug should be accompanied by a professional medical examination and regularly scheduled follow-up examinations so that lack of glycemic control, diabetes, pancreatitis, damage and disease, and/or other serious and life threatening side effects could be avoided or detected early;
- e. Failed to adequately warn the Plaintiff that use of the drug carried a risk of temporary and/or permanent disability due to diabetes, damage and disease, and/or other serious and life threatening side effects, including death;
- f. Failed to provide adequate post-marketing warnings or instructions after the Defendants knew or should have known of the significant risks of lack of glycemic control, diabetes, pancreatitis, damage and disease, and/or other serious and life threatening side

effects, including death;

- k. Failed to warn that off label use of the drug had not been adequately tested or studied as to safety in animals or humans; and
- l. Encouraged misuse and overuse, while underplaying the side effects, in order to profit from sales.

66. Defendants knew or should have known that the drug caused unreasonably dangerous risks and serious side effects, of which the Plaintiff could not be aware. Defendants nevertheless aggressively advertised, marketed, sold and/or otherwise distributed the drug and encouraged off label uses knowing that there were safer, alternative methods and/or products.

67. As a direct and proximate result of the wanton acts and/or omissions of Defendants, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, pancreatitis, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT VII
FRAUD, MISREPRESENTATION AND SUPPRESSION

68. Plaintiff restates each and every preceding allegation of this Complaint and incorporates

each by reference as though set forth in full herein and additionally or in the alternative, if same be necessary, further alleges as follows:

69. Defendants fraudulently, intentionally and/or negligently misrepresented to the Plaintiff, the safety and effectiveness of the drug at issue and/or fraudulently, intentionally, wantonly, and/or negligently concealed material information including adverse information regarding the safety and effectiveness of the drug.

70. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the drug had foreseeable defects, dangers, and/or characteristics that were other than what the Defendants had represented to the Plaintiff.

71. The misrepresentations and/or active concealment were perpetuated directly and/or indirectly by the Defendants.

72. The Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiff and/or Plaintiff's physician would rely on them, leading to the use of the drug by the Plaintiff.

73. At the time of Defendants fraudulent misrepresentations, the Plaintiff was unaware of the falsity of the statements being made and believed them to be true. Further, the Plaintiff had no knowledge of the information concealed and/or suppressed by Defendants.

74. The Plaintiff reasonably and justifiably relied on and/or was induced by the misrepresentations and/or active concealment, and on the absence of safety information which the Defendants did suppress, conceal and/or fail to disclose, to the Plaintiff's detriment.

75. Defendants had a post-sale duty to warn the Plaintiff about the potential risks and/or complications associated with the drug in a reasonable and timely manner.

76. The misrepresentations asserted and/or active omissions concealed by the Defendants constitute a continuing tort.

77. Defendants, individually and collectively, made the misrepresentations and/or actively

concealed this information with the intention and specific desire that the Plaintiff and/or Plaintiff's prescribing physician would rely on such information or the absence of such information in selecting the drug.

78. As a direct and proximate result of the fraudulent acts and omissions, suppression, and/or misrepresentations of the Defendants, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, pancreatitis, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

COUNT VIII
FICTITIOUS PARTIES

79. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

80. Plaintiff avers that the fictitious parties Defendant listed in this Complaint whose identities at this time are unknown, are also liable to the Plaintiff, individually and collectively, under each and every count listed above.

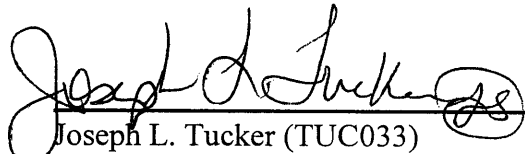
81. As a direct and proximate result of the actions, inactions, and/or omissions of the

Fictitious Defendants, Plaintiff has sustained serious and permanent injuries and damages including, but not limited to:

- a. hyperglycemia, diabetes, pancreatitis, and/or related injuries;
- b. other physical injuries;
- c. past and future health expenses including, without limitation, the cost of consultations with physicians and other medical treatment;
- d. physical and mental pain and suffering;
- e. mental anguish;
- f. loss of capacity for the enjoyment of life;
- g. loss of the ability to earn money in the future; and
- h. decreased life expectancy.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, both compensatory and punitive, as well as all costs of this action, and a trial by jury of all issues to be tried.

PLAINTIFF HEREBY DEMANDS TRIAL BY STRUCK JURY


Joseph L. Tucker (TUC033)
Attorneys for Plaintiff

JACKSON & TUCKER, P.C.

Black Diamond Building
2229 First Avenue North
Birmingham, Alabama 35203
Telephone: (205) 252-3535
Facsimile: (205) 252-3536

David P. Matthews
ABRAHAM, WATKINS, NICHOLS,
SORRELS, MATTHEWS & FRIEND
800 Commerce Street
Houston, TX 77002
Telephone: (713) 222.7211
Facsimile: (713) 225.0827

State of Alabama Unified Judicial System Form C-34 Rev 6/88	<h2 style="margin: 0;">SUMMONS</h2> <h3 style="margin: 0;">- CIVIL -</h3>	Case Number <div style="font-size: 1.5em; font-family: cursive;">CVD6-210</div>
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IN THE _____ Circuit _____ COURT OF _____ Lee _____ COUNTY

Plaintiff Andrea Holifield v. Defendant Eli Lilly & Company, Et al.

NOTICE TO _____ Peter Lusche, M.D., 3120 Frederick Road, Opelika, AL 36801

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY _____ JOSEPH L. TUCKER _____ WHOSE ADDRESS IS _____ Black Diamond Building 2229 First Avenue North, Birmingham, Alabama 35203

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN 30 DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☒ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☐ Service by certified mail of this summons is initiated upon the written request of _____ pursuant to the Alabama Rules of Civil Procedure.

Date 3/23/06 Corinne T. Hurst By: 88
 Clerk/Register

☐ Certified Mail is hereby requested. _____
 Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date).

Date _____

Address of Server _____

Server's Signature _____

Type of Process Server _____

State of Alabama Unified Judicial System Form C-34 Rev 6/88	<h2 style="margin: 0;">SUMMONS</h2> <h3 style="margin: 0;">- CIVIL -</h3>	Case Number <div style="font-size: 1.5em; font-family: cursive;">CVD6-210</div>
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IN THE _____ Circuit _____ COURT OF _____ Lee _____ COUNTY

Plaintiff Andrea Holifield v. Defendant Eli Lilly & Company, Et al.

NOTICE TO Eli Lilly & Company, National Registered Agents, Inc., 150 S. Perry St., Montgomery, AL 36104

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY _____ JOSEPH L. TUCKER _____ WHOSE ADDRESS IS Black Diamond Building 2229 First Avenue North, Birmingham, Alabama 35203

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN 30 DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of _____ Joseph L. Tucker _____ pursuant to the Alabama Rules of Civil Procedure.

Date 3/23/06 _____ Corinne T. Hurst _____ By: sz _____
 Clerk/Register

☒ Certified Mail is hereby requested. _____ Joseph L. Tucker _____
 Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

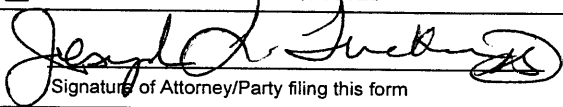
☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date)

Date _____

Address of Server _____

Server's Signature _____

Type of Process Server _____

State of Alabama Unified Judicial System Form ARCiv-93 Rev.5/99	COVER SHEET CIRCUIT COURT – CIVIL CASE (Not For Domestic Relations Cases)	Case Number <div style="border: 1px solid black; padding: 2px;"> C V 3006 210 - </div> Date of Filing: <div style="border: 1px solid black; padding: 2px;"> Month Day Year </div> Judge Code: <div style="border: 1px solid black; padding: 2px;"> - - - - - </div>
GENERAL INFORMATION		
IN THE CIRCUIT COURT OF _____ Lee County _____, ALABAMA (Name of County)		
Plaintiff: <u>Andrea Holifield</u> v. Defendant: <u>Eli Lilly & Company, Et al.</u>		
First Plaintiff: <input type="checkbox"/> Business <input checked="" type="checkbox"/> Individual <input type="checkbox"/> Government <input type="checkbox"/> Other First Defendant: <input checked="" type="checkbox"/> Business <input type="checkbox"/> Individual <input type="checkbox"/> Government <input type="checkbox"/> Other		
NATURE OF SUIT: Select primary cause of action, by checking box (check only one) the best characterizes your action:		
TORTS: PERSONAL INJURY <input type="checkbox"/> WDEA - Wrongful Death <input type="checkbox"/> TONG - Negligence: General <input type="checkbox"/> TOMV - Negligence: Motor Vehicle <input type="checkbox"/> TOWA - Wantonness <input checked="" type="checkbox"/> TOPL - Product Liability/AEMLD <input type="checkbox"/> TOMM - Malpractice-Medical <input type="checkbox"/> TOLM - Malpractice-Legal <input type="checkbox"/> TOOM - Malpractice-Other <input type="checkbox"/> TBFM - Fraud/Bad Faith/Misrepresentation <input type="checkbox"/> TOXX - Other: _____ TORTS: PERSONAL INJURY <input type="checkbox"/> TOPE - Personal Property <input type="checkbox"/> TORE - Real Property OTHER CIVIL FILINGS <input type="checkbox"/> ABAN - Abandoned Automobile <input type="checkbox"/> ACCT - Account & Nonmortgage <input type="checkbox"/> APAA - Administrative Agency Appeal <input type="checkbox"/> ADPA - Administrative Procedure Act <input type="checkbox"/> ANPS - Adults in Need of Protective Services	OTHER CIVIL FILINGS (cont'd) <input type="checkbox"/> MSXX - Birth/Death Certificate Modification/Bond Forfeiture Appeal/Enforcement of Agency Subpoena/Petition to Preserve <input type="checkbox"/> CVRT - Civil Rights <input type="checkbox"/> COND - Condemnation/Eminent Domain/Right-of-Way <input type="checkbox"/> CTMP - Contempt of Court <input type="checkbox"/> CONT - Contract/Ejectment/Writ of Seizure <input type="checkbox"/> TOCN - Conversion <input type="checkbox"/> EQND - Equity Non-Damages Actions/Declaratory Judgment/Injunction Election Contest/Quiet Title/Sale For Division <input type="checkbox"/> CVUD - Eviction Appeal/Unlawful Detainer <input type="checkbox"/> FORJ - Foreign Judgment <input type="checkbox"/> FORF - Fruits of Crime Forfeiture <input type="checkbox"/> MSHC - Habeas Corpus/Extraordinary Writ/Mandamus/Prohibition <input type="checkbox"/> PFAB - Protection From Abuse <input type="checkbox"/> FELA - Railroad/Seaman (FELA) <input type="checkbox"/> RPRO - Real Property <input type="checkbox"/> WTEG - Will/Trust/Estate/Guardianship/Conservatorship <input type="checkbox"/> COMP - Workers' Compensation <input type="checkbox"/> CVXX - Miscellaneous Circuit Civil Case	
ORIGIN (check one): F <input checked="" type="checkbox"/> INITIAL FILING A <input type="checkbox"/> APPEAL FROM DISTRICT COURT O <input type="checkbox"/> OTHER: R <input type="checkbox"/> REMANDED T <input type="checkbox"/> TRANSFERRED FROM OTHER CIRCUIT COURT		
HAS JURY TRIAL BEEN DEMANDED? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO Note: Checking "Yes" does not constitute a demand for a jury trial. (See Rules 38 and 39, Ala.R.Civ.P. for procedure)		
RELIEF REQUESTED: <input checked="" type="checkbox"/> MONETARY AWARD REQUESTED <input type="checkbox"/> NO MONETARY AWARD REQUESTED		
ATTORNEY CODE: <div style="border: 1px solid black; padding: 2px;">T U C 0 3 3</div> _____ Date: _____ Signature of Attorney/Party filing this form: 		
MEDIATION REQUESTED: <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> UNDECIDED		

FILED

MAR 23 2006

IN OFFICE
CORINNE T. HURST
CIRCUIT CLERK

SCANNED